



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/817,067	04/04/97	NIELSEN	ISIS-2112

MICHAEL P STRAHER
WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS
ONE LIBERTY PLACE 46TH FLOOR
PHILADELPHIA PA 19103

HM31/1123

EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 11/23/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/817,067

Applicant(s)
Nielsen et al.

Examiner
Ardin H. Marschel

Group Art Unit
1634



☒ Responsive to communication(s) filed on 4/8/98 (IDS) and amendment A, filed 8/5/98.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-22, 24, 30, 31, and 33 is/are rejected.

☒ Claim(s) 23, 25-29, 32, and 34-36 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 19 sheets.

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1634.

Applicants' IDS, filed 4/8/98, and arguments, filed 8/5/98, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polymers synthesized from monomers of instant claim 21 or similar monomers without the limitations given for parameters "y" and "z", it does not reasonably provide enablement for unspecified polymers as within the scope of instant claims 1-6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Several PNA polymers as instantly prepared from monomers which contain the structure as noted above have been prepared in the art as well as instantly described but it is noted that this chemistry requires protective groups on nucleobase as well as terminal amino groups and carboxyl groups to direct such

synthesis. This rejection is maintained and reiterated from the previous office action, mailed 2/3/98. Applicants argue that protective group practice is a well developed art. In response this is acknowledged but only directed to protection of reactive groups that will permit the synthesis of amide or peptide bonds while protecting carboxyl and or amino moieties on subunits as defined in instant claim 21 etc. Applicants have not pointed to support for synthesis of broader compounds as required for the practice of instant claims 1-6 thus resulting in maintaining this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 21, 22, and 24 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Summerton et al. (WO 86/05518).

This rejection is maintained and reiterated from the previous office action, mailed 2/3/98. Applicants argue that the definition of "conjugate" distinguishes over the cited benzoyl or nitrobenzoyl groups given in Summerton et al. In response benzoyl or nitrobenzoyl groups are aromatic lipophilic groups.

Clearly the benzene ring in such groups are aromatic and the instant specification states on page 24, lines 31-37, that benzene is also lipophilic. Aromatic lipophilic molecules are included within the argued definition of a "conjugate". Thus, the rejection is still deemed proper. Instant claims 21, 22, and 24 are added as rejected hereinunder due to the Figure 4 disclosure of Summerton et al. reading on these instant claims.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 28 of U.S. application serial number 08/595,387. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of each application include common PNA polymers with

conjugates bound thereto. This rejection is reiterated and maintained from the office action, mailed 2/3/98, as not being argued by applicants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21, 22, 24, 30, 31, and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 34-48 of U.S. application serial number 08/468,719. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of each application include common PNAs with conjugates bound thereto.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 23, 25-29, 32, and 34-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The disclosure is objected to because of the following informalities:

On page 7, line 10, the word "Preferebly" appears to be misspelled.

On page 7, line 20, the word "prefereably" appears to be misspelled.

On page 7, line 24, the word "inetegeter" appears to be misspelled.

On page 13, lines 34 and 35, the word "deravative" appears to be misspelled.

In claim 7, line 4, the word "inetegeter" appears to be misspelled.

Appropriate correction is required.

Enclosed is an executed PTO Form 1449 with four(4) U.S. Patent applications thereon cited lined through due to a lack of publication dates. These are serial numbers 07/782,374; 07/943,516; 08/117,363; and 08/275,951. These application disclosures are hereby indicated as having been considered.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Serial No. 08/817,067

- 7 -

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

November 23, 1998

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER